December 15 2004

Via fax

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004D-0440
Draft Guidance for Industry on Computerized Systems Used in Clinical Trials [Federal Register Volume 69, No. 191, pages 59239-59240, October 4, 2004]

Dear Sir/Madam:

PDA Japan appreciates the opportunity to comment on the above-referenced Draft Guidance entitled "*Computerized Systems Used in Clinical Trials*".

This draft guidance provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA.

We generally agree with the content in the guidance and offer the following comments for your consideration.

OVERALL COMMENTS:

1. This draft guidance uses "we recommend" instead of "should" in the current guidance. How can we interpret this difference?

2. There are several extracts of part 11, Electronic Records; Electronic Signatures - Scope and Application which interrupt our thinking to understand this draft guidance. Can't these explanatory descriptions be a little simpler?

SPECIFIC COMMENTS:

III. GENERAL PRINCIPLES
Line 80: *We also recommend that this documentation be retained as part of the study records.*

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Can we understand this documentation must be retained according to the guidance? If so and this documentation is retained/used electronically, is it within the scope of part 11 regulation?

III. GENERAL PRINCIPLES

Line 107: *We recommend that audit trials or other security methods used to capture electronic record activities document who made the changes, when, and why changes were made to the electronic record.*

Yes, "why" can be recorded in a 'procedural paper' audit trail. But automatic audit trail should record the changes without users intention, and we understand it is not easy to record "why". Or would you recommend making a system technically record reasons whenever changes occur?

V. STANDARD OPERATING PROCEDURES

Lines 138: *We recommend that SOPs be established for the following:*

Aren't other SOPs important such as training, archiving and retrieving?

VI. DATA ENTRY

Lines 200: *Even if there are no applicable predicate rule requirements, it may be important to have computer-generated, time-stamped audit trails or other physical, logical, or procedural security measures to ensure the trustworthiness and reliability of electronic records.*

Isn't it too demanding that "even if there are no applicable predicate rule requirements, it may be important to have computer-generated, time-stamped audit trails or other physical, logical, or procedural security measures to ensure the trustworthiness and reliability of electronic records."?

VII. SYSTEM FEATURES

Lines 258: *We recommend against the use of features that automatically enter data into a field when the field is bypassed.*

Aren't there any systems with more reasonable features that can automatically enter data into a field to avoid human errors when the field is bypassed?

VIII. SYSTEM SECURITY

Lines 312: *If a computerized system being used for a clinical study is part of a system normally used for other purposes, we recommend that efforts be made to ensure that the study software be logically and physically isolated as necessary to preclude unintended interaction with nonstudy software.*

It is difficult to imagine how to isolate logically and physically. You recommend "efforts be made to ensure that the study software be logically and physically isolated as necessary to preclude unintended interaction with nonstudy software", but is it really possible to separate hardware in the server while using a part of another software? How can we interpret this line?

DEFINITIONS

Lines 560: *Original data are those values that represent the first recording of study data.*

Aren't raw data and source data defined?

On behalf of PDA Japan, we appreciate the opportunity to comment on the *Draft Guidance for Industry on Computerized Systems Used in Clinical Trials* and are much obliged for your consideration.

Sincerely,

Daikitiro Murakami
Chairperson, Committee of Electronic Records & Electronic Signatures, PDA Japan